

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION UNDER 37 C.F.R. §1.131

APPLICANTS: Maria TORPO et al CONFIRMATION NO. 3792
SERIAL NO.: 10/562,302 GROUP ART UNIT: 3766
FILED: December 22, 2005 EXAMINER: Luther G. Behringer
TITLE: APPARATUS FOR DETECTING DIASTOLIC HEART FAILURE

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

SIR:

We, MARIA TORPO, MALIN ÖHLANDER, ANDERS BJÖRLING, and KARIN LJUNGSTRÖM, hereby declare and state as follows:

1. We are the inventors of the subject matter disclosed and claimed in the above-referenced United States patent application.
2. The subject matter disclosed and claimed in the above-referenced United States patent application was conceived and reduced to practice in Sweden by us in the employ of St. Jude Medical AB.
3. The subject matter disclosed and claimed in the above-referenced United States patent application was the subject of two invention disclosures that were received by the Patent Department of St. Jude Medical AB on September 17, 2003. Copies of those invention disclosures are attached hereto as Exhibit A and Exhibit B.
4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this verified statement is directed.

DATE: _____

MARIA TORPO

DATE: _____

MALIN ÖHLANDER

DATE: Feb. 13, 2009

Anders Björklund
ANDERS BJÖRKLUND

DATE: Feb 16, 2009

Karin Ljungström
KARIN LJUNGSTRÖM

Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this verified statement is directed.

DATE: Feb 18, 2009

Maria Torpo
Maria Torpo

DATE: Feb 18, 2009

Malin Öhlander
Malin Öhlander

DATE: Feb. 13, 2009

Anders Björklund
Anders Björklund

DATE: _____

KARIN LJUNGSTRÖM

(To be sent in a sealed envelope as well as electronically to the Patent Dept. of St. Jude Medical AB)

For Patent Department use only

<input checked="" type="checkbox"/> Confirmation of receipt sent to the Inventor(s)	Signature: CB	Disclosure No.: A03E2093
<input type="checkbox"/> Copy sent to the Manager of the Inventor(s)	Signature: CB	Date Received: RECEIVED
<input type="checkbox"/> Copy sent to the Patent Committee	Signature: CB	2003-09-17 St. Jude Medical AB Patent Department

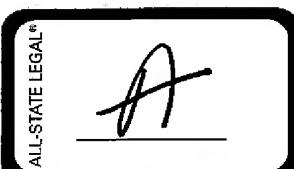
d Symlar 2003-10-01

Title of the Invention:
Measurement of DT as DHF surrogate

Name of Inventor(s): Maria Torpo, Malin Öhlander, Anders Björling, Karin Ljungström	Date: 2003-09-17
<input checked="" type="checkbox"/> St. Jude Medical AB <input type="checkbox"/> St. Jude Medical Sweden AB* <input type="checkbox"/> Other St. Jude Medical company* <input type="checkbox"/> Non-employee*	

* Assignment has to be filled out. Please contact the Patent Department of St. Jude Medical AB.

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Decision/Recommendation by the Patent Committee:	Degree of priority: A	Category: A
<input checked="" type="checkbox"/> Rights of Invention assigned/confirmed to St. Jude Medical AB. <input type="checkbox"/> To be published. <input checked="" type="checkbox"/> See remarks below.	Date: 03/00	
Technological Classification: Pecency 100 hours failure	IRM Scores:	US Class: 607/9
IPC:		
PUS: S.N., K.L., M.L., O.S., SK, NO. : 7a Till Symlar A stroke Diastolic Ventricular Failure		
		

Disclosure No.:

A03E2093

1. Problem to be solved by the Invention:

In the space provided below, briefly describe the problem your invention is trying to solve.

The invention will measure and record the E-wave deceleration time, DT, in order to provide a Diastolic Heart Failure (DHF) surrogate. By recording changes in DT over time, a measurement of how the disease progresses is provided. Also, in patients that do not have DHF it is possible to detect if the disease originates, thus allowing medical attention.

2. Background:

In the space provided below, briefly describe the background information or the state of the art; patent documents, articles, etc.

Many pacemaker patients have or are at risk of developing DHF, Diastolic Heart Failure. Early detection of DHF and detection of the progress of DHF is highly eligible so that the right treatment can be employed for the patient. There are many parameters that indicate the progress of DHF, so called DHF surrogates. One of them is the E-wave deceleration time, DT (also referred to as the "Dec time"). DT is defined as the time from when the blood velocity through the mitral valve has reached its peak velocity to the time it reaches zero. If zero velocity isn't obtained due to A-wave influence, the time is calculated by interpolation, see figure 1. Detecting and measuring the DT would provide a DHF surrogate, thus providing a way to measure the progress or detect the origin of DHF.

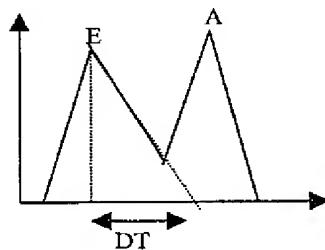


Figure 1: A schematic picture of the blood velocity through the mitral valve as measured by echocardiography.

The progress of Diastolic Heart Failure can be divided into three phases and each of these phases causes a change in the DT, see figure 2 (taken from Maria Torpo's report on DHF). The first phase of DHF is the one referred to as "Impaired relaxation", during this phase the DT is much longer than in a normal heart. After this phase the disease progresses into a phase called "Pseudonormal" where the heart compensates and DT returns to more normal values (proximate to the DT of the normal heart). This phase is followed by the final stage of DHF called "Restrictive". During the restrictive phase DT changes is shorter than the DT of the normal heart.

Disclosure No.:

AO3E2093

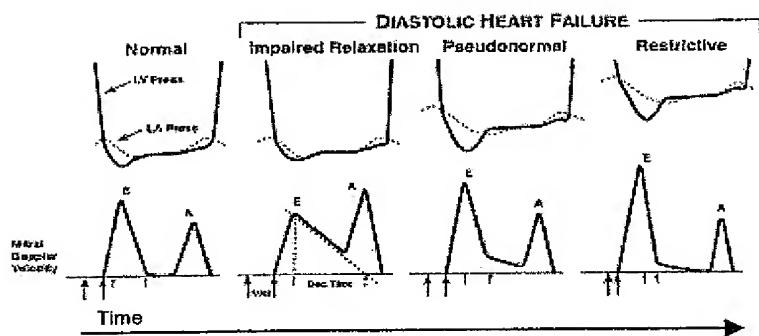


Figure 2. Changes in the DT (deceleration time) during DHF development.

3. Description of Invention:

In the space provided below, (attach additional sheets as necessary), provide a complete and concise description of your invention. Such description should include (to the extent known at the time of this disclosure) the nature, structure, operation, and physical, chemical, biological, or electrical characteristics of the invention, with sketches and/or schematic diagrams where possible. Include the novel features, advantages and any planned uses of this invention in a product. Attach any additional materials, which may assist in explaining the invention, and identify below.

Number of pages attached: _____

The pacemaker will, with the use of sensors, its IEGMs or impedance-measurements, measure or calculate the DT at given time-intervals and either store it or the changes in the DT in the memory of the pacemaker. Once the patient comes in for a follow-up, the DT development over time will be downloaded from the pacemaker and the treating physician can evaluate the results and view the progression or regression of the disease.

If the pacemaker detects a change in the DT that may be an indication that the patient is developing DHF or if the patient is progressing into a new phase of DHF, the pacemaker can send out an alert that the patient should be called in for a follow-up.

The surrogate could also be used for optimising future DHF pacing therapy or for optimising pacemaker settings.

Disclosure No.:

A03E2093

4. Has the invention been evaluated (tested/manufactured)? If Yes; provide the date, result, etc.	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes;	
5. Is the invention intended to be used for/in connection with any products, projects, etc? If Yes; provide name of the product/project, etc.	
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes; Future implantable devices	
6. Has the invention been published/used in any products? If Yes; provide the date of serial production start/date and type of publication.	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes;	
7. Is the invention known by anyone outside St. Jude Medical AB, St. Jude Medical Sweden AB or any other St. Jude Medical company? If Yes; mark the applicable alternative.	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes; a) <input type="checkbox"/> A valid confidentiality agreement exists. b) <input type="checkbox"/> No confidentiality agreement exists.	
8. Is the invention within your job area?	Is the invention within St. Jude Medical's area of business?
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

Name: Maria Torpo	Title:	Employee No.: 7327	Department: Research
Private address: Duvkullavägen 42B, 2 tr 172 37 Sundbyberg	Nationality: Swedish	Date of birth: 3 March 1975	
Signature: 			
As to my knowledge, only the named inventors have contributed to the invention.			
Name: Malin Öhlander	Title:	Employee No.: 7255	Department: Research
Private address: Mariatorget 6a, 3trög 118 48 Stockholm	Nationality: Swedish	Date of birth: 21 December 1976	
Signature: 			
As to my knowledge, only the named inventors have contributed to the invention.			
Name: Anders Björling	Title: Scientist	Employee No.: 2219	Department: Research
Private address: Handbollvägen 24G 175 53 Järfälla	Nationality: Swedish	Date of birth: 1 July 1977	
Signature: 			
As to my knowledge, only the named inventors have contributed to the invention.			

For further Inventors; see additional sheet.

Disclosure No.:

A03E2093

Name: Karin Ljungström	Title: Research Director	Employee No.: 2049	Department: Research
Private address: Albert Landbergs gränd 34 165 70 Hässelby	Nationality: Swedish	Date of birth: Jan 4, 1959	
Signature: 			
As to my knowledge, only the named inventors have contributed to the invention.			
Name:	Title:	Employee No.:	Department:
Private address:	Nationality:	Date of birth:	
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 For further Inventors; see additional sheet.



INVENTION DISCLOSURE

(To be sent in a sealed envelope as well as electronically to the Patent Dept. of St. Jude Medical AB)

For Patent Department use only

<input checked="" type="checkbox"/> Confirmation of receipt sent to the Inventor(s)	Signature: 	Date Received:	RECEIVED
<input checked="" type="checkbox"/> Copy sent to the Manager of the Inventor(s)	Signature: 	2003-09-17	
<input checked="" type="checkbox"/> Copy sent to the Patent Committee	Signature: 	St. Jude Medical AB Patent Department	

at Sylmar 2003-10-06

Title of the Invention: Measuring/calculating IVRT as a CHF surrogate	Date:
Name of Inventor(s): Maria Torpo, Malin Öhlander, Anders Björling, Karin Ljungström	2003-09-17
<input checked="" type="checkbox"/> St. Jude Medical AB <input type="checkbox"/> St. Jude Medical Sweden AB* <input type="checkbox"/> Other St. Jude Medical company* <input type="checkbox"/> Non-employee*	

* Assignment has to be filled out. Please contact the Patent Department of St. Jude Medical AB.

Decision/Recommendation by the Patent Committee: <input checked="" type="checkbox"/> Rights of Invention assigned/confirmed to St. Jude Medical AB. <input type="checkbox"/> To be published. <input checked="" type="checkbox"/> See remarks below.	Degree of priority: 17	Category: 17
Technological Classification: Pacem 106 heart failure	Date: 203001	Signature: Re Esq (act)
	IRM Scores:	US Class: 607/9
		IPC:
<i>ALL STATE LEGAL®</i> 		

Disclosure No.:

A03E2094

1. Problem to be solved by the Invention:

In the space provided below, briefly describe the problem your invention is trying to solve.

The invention will measure and record the isovolumic relaxation time, IVRT, in order to provide a Diastolic Heart Failure (DHF) surrogate. By recording the changes in IVRT over time a measurement of how the disease progresses is provided. Also, in patients that do not have DHF it is possible to detect if the disease originates thus allowing medical attention.

2. Background:

In the space provided below, briefly describe the background information or the state of the art; patent documents, articles, etc.

Many pacemaker patients have or are at risk of developing DHF, Diastolic Heart Failure. Early detection of DHF and detection of the progress of DHF is highly eligible so that the right treatment can be employed for the patient. There are many parameters that indicate the progress of DHF, so called DHF surrogates; one of them is the isovolumic relaxation time, IVRT. Detecting and measuring the IVRT would provide a DHF surrogate, thus providing a way to measure the progress or detect the origin of DHF.

Diastolic Heart Failure can be divided into three phases and each of these phases causes a change in the IVRT, see figure 1 (taken from Maria Torpo's report on DHF). The first phase of DHF is the one referred to as "Impaired relaxation", during this phase the IVRT is longer than in a normal heart. After this phase the disease progresses into a phase called "Pseudonormal" where the heart compensates and IVRT returns to more normal values (proximate to the IVRT of the normal heart). This phase is followed by the final stage of DHF called "Restrictive". During the restrictive phase IVRT changes is shorter than the IVRT of the normal heart.

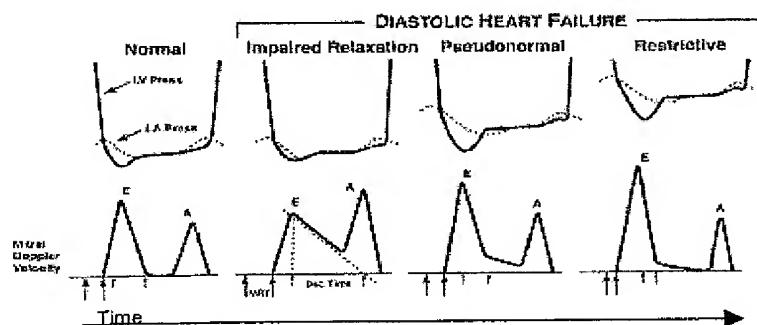


Figure 1. Changes in the IVRT during DHF development.

Disclosure No.:

A0352094**3. Description of Invention:**

In the space provided below, (attach additional sheets as necessary), provide a complete and concise description of your invention. Such description should include (to the extent known at the time of this disclosure) the nature, structure, operation, and physical, chemical, biological, or electrical characteristics of the invention, with sketches and/or schematic diagrams where possible. Include the novel features, advantages and any planned uses of this invention in a product. Attach any additional materials, which may assist in explaining the invention, and identify below.

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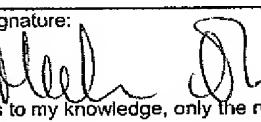
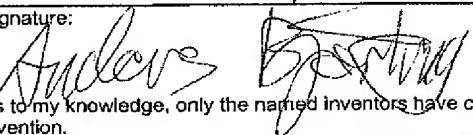
The pacemaker will, with the use of sensors, its IEGMs, impedance-measurements or other, measure or calculate the IVRT at given time-intervals and either store it or only the changes in the IVRT in the memory of the pacemaker. Once the patient comes in for a follow-up, the IVRT development over time will be downloaded from the pacemaker and the treating physician can evaluate the results and view the progression of the disease.

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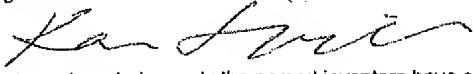
A0362094

4. Has the invention been evaluated (tested/manufactured)? If Yes; provide the date, result, etc.	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes;	
5. Is the invention intended to be used for/in connection with any products, projects, etc? If Yes; provide name of the product/project, etc.	
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes; Future implantable devices	
6. Has the invention been published/used in any products? If Yes; provide the date of serial production start/date and type of publication.	
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Name: Maria Torpo	Title:	Employee No.: 7327	Department: Research
Private address: Duvkullavägen 42B, 2 tr 172 37 Sundbyberg	Nationality: Swedish	Date of birth: 3 March 1975	
	Signature: 	As to my knowledge, only the named inventors have contributed to the invention.	
Name: Malin Öhlander	Title:	Employee No.: 7255	Department: Research
Private address: Mariatorget 6a, 3trög 118 48 Stockholm	Nationality: Swedish	Date of birth: 21 December 1976	
	Signature: 	As to my knowledge, only the named inventors have contributed to the invention.	
Name: Anders Björling	Title: Scientist	Employee No.: 2219	Department: Research
Handbollvägen 24 G 175 53 Järfälla	Swedish	1 July 1977	
	Signature: 	As to my knowledge, only the named inventors have contributed to the invention.	

For further Inventors; see additional sheet.

Disclosure No.:
A03E2094

Name: Karin Ljungström	Title: Research Director	Employee No.: 2049	Department: Research
Private address: Albert Landbergs gränd 34 165 70 Hässelby	Nationality: Swedish	Date of birth: Jan 4 1959	
Signature: 			
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Private address:	Nationality:	Date of birth:	
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